any documents which provided additional guidance qualifying or limiting the type of experiments requiring approval. Such guidance normally would have been transmitted through the Office of the Chief Chemical Officer to the Commander of the Chemical Corps Research and Engineering Command located at what is now Edgewood Arsenal. Records do indicate that on 24 July 1953, after receiving guidance from the Chief Chemical Officer, the Commander of the Chemical Research and Engineering Command notified the Commander of the Chemical Corps Medical Laboratories that the policies and procedures set forth in Chief of Staff Memorandum 385 were effective immediately and would govern the use of volunteers in all present and future experimental research.[12] The Commander also directed that research plans and requests for approval to conduct experiments using human volunteers be submitted by 7 August 1953, and that until such time as new approval was granted all experimentation using volunteers would be stopped. This action directed immediate compliance without exception to the new policy.

Initial Request to Use Volunteers

On 7 August 1953 the Medical Laboratory Commander submitted a request for approval to conduct seven research projects. Although not specifically stated, it was implied that these experiments had been in progress at the time the 24 July 1953 letter was received. The seven research projects for which approval was requested were:

a. Retention of nerve gas vapor in human respiratory tract.

b. Behavior of nerve gas liquid on the human skin.

c. Effects of nerve gas on the nervous and mental functions in man.

d. Effects of nerve gases and of therapeutic agents on visual efficiency.

e. Evaluation of candidate therapeutic agents in man.

f. Sensory threshold effects of phosgene oxime in man.

g. Comparative effects on skin of vesicant liquids, vapors, and aerosols.[13]

The Medical Laboratory Commander in his request for approval of the research plans included his interpretation that the "use of volunteers in research" applied to the exposure of individuals to the hazards of toxic chemicals, whether they were standard or candidate chemical warfare agents, or standard or chemical therapeutic agents. The Laboratory Commander expressed an assumption that the Chief of Staff directive requiring Secretary approval did not include studies of the physiological aspects of protective material, including the protective mask, since such studies did not have to involve exposure to toxic chemicals.

The Commander, Chemical Corps Research and Engineering Command, the Chief Chemical Officer, and The Surgeon General reviewed the proposed plan and recommended to the Secretary that it be approved. The Surgeon General in his comments provided an opinion that the provisions of the Chief of Staff Memorandum 385 would apply in the event toxic chemicals were used in gas mask tests. A memorandum to Chief of Staff, dated 5 November 1953, signed by the Secretary of the Army, Robert T. Stevens, granted approval to conduct the requested research programs using human volunteers.[14] A synopsis of the Chemical Corps plan, which listed the seven investigative studies, was attached as an inclosure to the approval memorandum and contained a statement to the effect that the basic directive did not include studies of the physiological aspects of protective materials, including the protective function of the gas mask, unless such studies included exposure to toxic chemicals. Although the copy of the Chemical Corps plan referred to in the Secretary of the Army's memorandum could not be located, other documents indicated that the approved plan contained basically the same data submitted by the Medical Laboratory on 7 August 1953. Further support of that contention was contained in a 24 December 1953 letter from the Office of the Chief Chemical Officer to the Commander, Chemical Corps Research and Engineering Command, in which approval of the request of 7 August 1953 was granted. This particular letter approved all seven investigative study requests without modification or qualification; it confirmed the assumption that studies involving physiological aspects of protective material were not within the intent of the Chief of Staff Memorandum 385, unless exposure to toxic chemicals was involved; it directed that Army contractors must abide by the same basic principles and safeguards governing military researchers; and it specified that the fact that the Chemical Corps was using human volunteers in research was, of itself, unclassified.[15] This downgrading of classification apparently was attributable to the Secretary's earlier concern about the level of classification, which culminated in a Secretary of the General Staff Memorandum, dated 16 October 1953, downgrading Chief of Staff Memorandum 385 from "TOP SECRET" to "CONFIDENTIAL."[16] It appeared that the initial high classification afforded the subject may have been partially responsible for the lack of complete documentation and for early misinterpretations of the policy.

Policy interpretations are mentioned at this time because there was evidence that at least one research project was not terminated pending submission and approval of the research plan in accordance with Chief of Staff Memorandum 385. Specifically, an operation code named "TOP HAT" was conducted at the Chemical Corps School, Fort McClellan, AL, between 15 and 19 September 1953.[17]

This research project, which was termed a "local field exercise," involved the use of Chemical Corps troops in testing methods of decontaminating biological warfare agents, mustard gas, and nerve gas. A review of the scant literature available on the exercise indicated that it was conducted in contravention of the intent of the Department of Defense and Department of the Army policies. While it is possible that a separate request for approval may have been submitted and subsequently retired and/or destroyed, it is more logical to assume that the project was considered to fall within a "line of duty" exercise for Chemical Corps troops and interpreted as not subject to the provisions of policies governing the "use of volunteers in research." This conclusion is not offered as an excuse for an exercise in which soldiers were exposed to toxic chemical agents without proper authorization and without their consent, but rather to emphasize the extreme difficulty of attempting to implement a complex policy by means of a relatively simple, but highly classified directive.

Another observation of import concerns the seven investigative studies which were forwarded for approval and which appeared to be a request for approval of experiment with a "class" of drugs rather than a request for research involving a specific chemical agent. For example, the first of the seven investigative studies, "Retention of Nerve Gas Vapor in the Human Respiratory Tract," failed to specify which of the several available nerve gas agents would be used and under what circumstances. Since the nerve gas agents varied significantly in toxicity, it would appear extremely difficult for The Surgeon General to conduct a thorough evaluation of the proposal without knowing the specific chemical nerve agent to be used in the experiment. Again, there may have been additional correspondence and conferences answering these various questions about the agent to be used and the emergency treatment measures to be available on site prior to The Surgeon General recommending approval, however, no records of such were found. Thus, the available records gave the impression that the submission of the initial request amounted to nothing more than a perfunctory action for the purpose of obtaining blanket approval for ongoing research projects.

Medical Volunteer Program

By 1954 the Chemical Corps had established a framework within which to conduct human experimentation, however, they lacked an adequate pool of volunteers. There were indications some experimentation was being conducted using enlisted personnel assigned to Edgewood and technicians assigned to the laboratories. However, this source was extremely limited and could not support the type research program envisioned.

In 1955 it was decided that the most practical source of volunteers would be enlisted men stationed at Army installations in the vicinity of Edgewood Arsenal. The Medical Laboratories formed an orientation team to visit Second Army Headquarters at Fort George G. Meade and solicit the support of the commander. The mission was successful. In April 1955 HQ, Second Army, published a directive to its major installation commanders encouraging them to publicize the program in an attempt to provide Edgewood Arsenal 20 volunteers each month for a period of 30 days temporary duty (TDY).[18]

The first contingent of 16 soldiers from Second Army Headquarters arrived at the Army Chemical Center (Edgewood Arsenal) on 2 May 1955.[19] For a brief period it appeared that the Medical Laboratories had established a complete, viable program, i.e., authority to use humans in research; a proper medical staff to conduct the research; and a steady supply of volunteers. However, within a few months more urgent priorities for Second Army's personnel resources inhibited the flow of volunteers.[3] In an effort to overcome this shortfall, the Chief Chemical Officer requested the support of the Quartermaster General, the Chief, Corps of Engineers, the Chief of Ordnance, and the Chief Signal Officer. This action resulted in volunteers coming from Fort Knox, KY, Fort Lee, VA, Fort Eustis, VA, Fort Belvoir, VA, Fort Monmouth, NJ, and Aberdeen Proving Ground, MD, in addition to those already committed by Fort Meade.

Psychochemical Drugs

On 7 September 1955 the Commander of the Medical Laboratories formally requested permission to use volunteers in research involving nonlethal psychochemicals.[20] His request, titled, "Additional Use of Volunteers in Research," was submitted to the Commanding General, Research and Engineering Command, who concurred in the request, as written, and forwarded it to the Chief Chemical Officer, Department of the Army.[21] Prior to the request being prepared and forwarded, there was a considerable body of research data concerning the effects of psychochemicals on humans available to the Chemical Corps Medical Laboratory, to include data obtained as a result of actual experimentation conducted by civilian hospitals and universities working under Army contracts.

Some of the events which preceded this request had a direct bearing on it and on subsequent actions involving psychochemicals. Several months prior to the Medical Laboratories' request to use volunteers in psychochemical research, the Chairman of the Technical Advisory Panel on Biological and Chemical Warfare, Office of the Assistant Secretary of Defense (R&D), appointed an "Ad Hoc Study Group on Psychochemical Agents" to evaluate the military potential of this type of chemical warfare. Their report, known as the "Wolff Report," after the name of the committee chairman, was published in November 1955 and presented specific recommendations for the conduct of future research involving psychochemical agents.[22] The committee concluded that experiments with psychochemical agents, of which LSD appeared to be the most promising, should be carried out with volunteer units as soon as practicable. In this regard, the Study Group also prepared and recommended the implementation of a detailed plan for the conduct of small unit experiments. Reference to the "Wolff Report" was necessary at this point because a review of the actions surrounding the submission of the September 1955 request for "Additional Use of Volunteers" gave the impression that staffing of the request was held in abeyance pending release of the report. It apparently was known beforehand that the Study Group would not only favor testing of psychochemicals on humans, but also would recommend that tests be conducted to determine the drug's effect on small military unit operations. Records also indicated that several months prior to the September 1955 request being approved, advance planning was underway to implement the testing of small units, as recommended by the "Wolff Report."

In January 1956 the Office of the Assistant Chief Chemical Officer for Planning and Doctrine reviewed the "Wolff Report" and commented on the recommendation which proposed that, prior to a military group being administered LSD, they should be given a carefully prepared training lecture on the effects of LSD. The reviewer stated that: "in view of the fact that a great many of the effects observed in the group may be the result of suggestion (placebo effect) it would appear desirable to have one control group which has neither been given a training lecture on LSD-25, nor any information as to the symptoms of the drug being administered. Symptoms due to suggestion would thus be reduced to a minimum and at the same time a more realistic combat situation would be utilized since it is assumed that enemy personnel, under combat conditions, would not have recently been briefed on the effects of LSD-25."[23] It is not known whether the reviewer in this instance would have caused the drug to be administered to all of the volunteers or to selected members of each group. Implicit in the comment, however, is the theme that, from the military standpoint, a lack of knowledge on the part of the volunteer was necessary for a realistic experiment. Neither the correctness of the comment nor the value of the added realism is at issue. What is involved is that in spite of clear guidelines concerning the necessity for "informed consent," there was a willingness to dilute and in some cases negate the intent of the policy. It will be demonstrated again during the discussion of the specific experiments that this attitude of selective compliance was more of the norm than the exception. Other evidence indicated that in 1956, prior to the approval to use human volunteers in testing of psychochemical drugs, research investigators at Edgewood Arsenal attempted to secure permission to employ a NIKE site crew as the small unit to be used in the type experiments recommended by the "Wolff Report."[24]

Another example of selective compliance with existing policy occurred in February 1956. A memorandum from the Deputy Chief Chemical Officer for Scientific Activities to the Commander of the Research and Development

Command recommended that the Chemical Corps scientific studies of LSD, a U.S. patented compound, be continued; that for military security reasons the owner of the patent not be advised of the present and possible future interest in the compound; and that a careful record of the quantities synthesized be maintained. This recommendation was made after a legal opinion was received from the Chemical Corps Patent Agency which, in effect, stated that use of the patent compound in the manner intended would be an infringement of the patent owner's rights and actionable by the patent owner; that based on this "the Chemical Corps may use the invention set forth in the reference patent and its only liability for so doing will be a requirement to pay a reasonable sum for so doing." It further opined that "governmental use of the invention need not be disclosed to assignee where such action would compromise security." [25] It is not known if the patent owner of LSD ever received notification of the use of his patent or reimbursement for such use. The point of this example is not simply to show possible violation of patent rights, but to again demonstrate the existence of a frame of mind and purpose which fostered a willingness to bend or break rules and policies so as to insure mission accomplishment; a continuing reliance on the "end justifies the means."

In March 1956 the staffing action on the September 1955 request for "Additional Use of Volunteers," which had apparently stopped pending receipt and review of the "Wolff Report," resumed when the Chief Chemical Officer forwarded the proposal to The Surgeon General, requesting his comments and concurrence. The forwarding indorsement pointed out that the Chemical Corps was conducting research investigations, using volunteers, in defense against chemical warfare, and that a small portion of such research, conducted entirely by highly qualified contractors, involved experimentation with psychochemical drugs. This research was reportedly authorized by the Secretary of the Army in his 5 November 1953 memorandum.[26] However, a review of the referenced memorandum does not indicate any reference to psychochemicals. To the contrary, the approved plan contained seven specific experiments involving nerve agents, oximes, and vesicants. Further, the Secretary of the Army directed that the same principles and safeguards which applied to the Department of the Army would apply equally to contracts awarded to outside contractors. The Chief Chemical Officer further stated that the increasing importance of the "minimum destruction" concept and the need for a defense against agents causing temporary incapacitation had led to the need for a concentrated study of psychochemical agents. Studies which, for the first time, would involve the use of psychochemicals on volunteers in the Chemical Corps laboratories. The proposed plan for testing psychochemicals provided the protocol, the name of the medical doctor in charge, and a proposal for the conduct of operational exercises to determine the vulnerability of military personnel to psychochemical agents in various military exercises. These exercises included: command post operations;

logistical exercises; squad drills; bridging operations; and fire direction center operations. Moreover, the request estimated that 200 volunteers would be required in the first year of experiments. This request was for a "class" of chemicals (psychochemicals) and for types of experiments rather than specific drugs for a specific experiment. This procedure, although not specifically prohibited by existing policy, appeared to be a departure from the intent of the policy, and as such did not provide those in the approval chain with a clear or complete picture of what actually was being proposed as it related to the volunteer. There was no evidence found indicating that objections or questions were raised concerning this lack of specificity. Although, on 11 April 1956 The Surgeon General, in his reply, did refer to earlier discussions and correspondence on the subject matter and that the proposal, as submitted, was a satisfactory development of ideas discussed, provided for adequate safeguards, and recommended approval by the Secretary of the Army.[27] However, no record of the earlier discussions or correspondence was located, nor was there other evidence discovered which would indicate that those higher in the chain of approval, to include the Secretary of the Army, received information other than that contained in the proposal and The Surgeon General's review. It was recognized that informal coordination or briefings could have provided more of the details as to the specific drug to be used. However, subsequent events do not reinforce this supposition. On 17 May 1956 the Director of Research and Development, in a memorandum to the Chief of Staff, U.S. Army, approved the plan as submitted, although there was a specific requirement that the Secretary of the Army must approve, in writing, each proposed use of human volunteers.[28] There was evidence that this deviation from policy was questioned immediately by responsible Chemical Corps personnel. However, a memorandum for record indicated that as a result of a discussion between a Chemical Corps legal advisor and an officer in the Director of Research and Development office, it was determined that the approval action was proper. There was no evidence found which would indicate that the Secretary of the Army approved the proposal, either in writing or orally; or that he delegated approval authority to the Director, Research and Development; or that he even had knowledge of the approval made in his stead. Several witnesses stated that since the Director of Research and Development was a member of the Secretary's staff, as the forerunner of the current Assistant Secretary of the Army for Research and Development, he would have been in the proper execution of his responsibilities when he approved the request in the name of the Secretary.[30]

Nevertheless, on 24 May 1956 the Medical Laboratory at Edgewood Arsenal was notified that the psychochemical testing plan had been approved. Since approval came through normal command channels, there would have been no reason for the Medical Laboratory Commander to question the authority to proceed with the planned experiments.[29] This request and subsequent approval appeared to have established two precedents:

(1) requests for the use of volunteers in drug testing could be approved on a "class" basis without specific mention of the wide variety of drugs involved, or their individual potential effects; and (2) regardless of earlier guidance, all protocols did not require the written approval of the Secretary of the Army. Undoubtedly, these two precedents laid the groundwork for future dilution of what had originally appeared to be clear and unequivocal centralized control of the authority to use volunteers.

Army-Wide Recruitment

Available records indicate that by early 1957 inadequate numbers of volunteers were being made available to the Chemical Corps for conduct of human experiments. Thus, in April 1957 The Adjutant General of the Army directed the Army area commanders in the United States to establish a program to obtain volunteers for use at the Chemical Warfare Laboratories at Edgewood Arsenal.[31] This document cited the need for 50 volunteers per month and established a schedule for the six Army areas to furnish volunteers for 30-day TDY periods. The directive gave Chief of Staff Memorandum 385, dated 30 June 1953, as authority to conduct this program. It emphasized that voluntary consent of the human subject was absolutely essential; and stated that in all experiments involving volunteer subjects, the individual would be thoroughly informed of all procedures and what to expect during each test. Furthermore, the volunteer would be free to determine whether or not he desired to participate.

On 11 July 1957 the Chief Chemical Officer wrote a letter addressed to all Chemical Officers in the Zone of Interior (ZI), in which he encouraged them to energetically support the volunteer program, emphasizing the importance of the volunteer's contribution to the national defense effort.[32]

Air Force-Navy Participation

During the same timeframe, the United States Air Force and the Department of the Navy were invited to participate in the volunteer program by sending 10 men each month. Records reflected that the Air Force contributed volunteers starting in November 1957; the Navy apparently elected not to join the program at this time.[3] Available records reflected that between May 1955 and December 1957 approximately 540 volunteers were employed in the program at Edgewood Arsenal; 14 of these were reported to have been from the Air Force.[3] However, indications were that this figure did not include the assigned technical assistants and researchers who "informally" volunteered. However, records indicated an additional project involving Air Force and Army participation in August 1961 when the Chemical Research and Development Command submitted a protocol for "experimental exposures of men to propellant vapors." This experiment was reported as an Air Force research project conducted with the use of Air Force volunteers.[47] Although there was evidence that the protocol was submitted through U.S. Army Chemical Corps channels for the purpose of receiving Secretary of the Army's approval, there were no records discovered which indicated that such approval was granted. It is possible that approval was granted and records not retained in historical files. However, the important point is not the absence of records, but that responsible investigators and commanders recognized that this type of research test was not included within the broad authority previously received.

V-Agent Studies

Further interpretation of which experiments actually required personal approval by the Secretary of the Army was found in the documentation concerning approval to conduct volunteer tests with V-agents (lethal nerve agents). In May 1958 the Commander, Chemical Warfare Laboratories, submitted a request, subject: "Use of Volunteers in Research on V-Agents," through Chemical Corps Command channels, requesting authority to test V-agents in man. Specified in the proposal was the statement that one of the proposals, submitted and subsequently approved by the Secretary of the Army in November 1953, included the use of G-agents (nerve agents), which are highly toxic organo-phosphorus compounds. The request continued that even more effective organo-phosphorus compounds, known as V-agents, had been synthesized.[33] The Chief Chemical Officer, in forwarding the request to The Surgeon General for his comments and/or concurrence, stated that research investigations being conducted under the 5 November 1953 approval involved G-agents and implied that the request to use V-agents was simply a logical extension of the initial plan. In June 1958 the Chief, Research and Development Division, Office of The Surgeon General, responded to the May 1958 request by pointing out that a critical review could not be made on the basis of information provided in the proposal, however, it did state that the proposal, as written, satisfied the minimum requirements under Chief of Staff Memorandum 385. The Surgeon General commented that since human studies on V-agents were a logical extension of the nerve gas studies previously approved by the Secretary of the Army, that the same responsible medical doctor was in charge, and the investigation would adhere to the provisions of Chief of Staff Memorandum 385, then it was believed that no new authorization was required.[34] The requested comments were returned to the Chief Chemical Officer, and ultimately the research project involving the use of V-agents in human volunteers began.

In reviewing The Surgeon General's comments in this instance, it was noted that there was reference to more stringent safeguards used in the volunteer program with BW agents. These included: submission of a protocol for each new series or phase of study; a critical review by The Surgeon General to insure compliance with Chief of Staff Memorandum 385 before proceeding; and continual review of experimental results. This indication of the use of a double standard in implementing policy on use of volunteers was not further explained.

The Surgeon General's comments point out this difference very succinctly and ultimately agreed with the original contention that it was a logical extension of G-agent research, requiring no further authorization. Documentation was not found which would explain how after a proposal to employ a more highly toxic agent on humans was received, and the reviewing official in The Surgeon General's office concluded initially that a review or constructive comments could not be made on the basis of the information provided, and still be adequate to satisfy the minimum requirements of the Chief of Staff Memorandum 385 policy. In spite of these unanswered critical questions, the reviewer, in effect, agreed with the proposal and added weight to the interpretation of policy made by the Chemical Corps.

Policy Interpretations

Meanwhile, in the fall of 1957 the U.S. Army Chemical Research and Development Command had directed the term K-agent be used instead of psychochemical agent. Although these terms continued to be used interchangeably, it was noted that at this point in time the Medical Laboratory at Edgewood Arsenal had approval to use volunteers in experiments involving three classes of compounds: G-agents; V-agents; and K-agents. However, the Secretary of the Army actually had signed only the authorization for seven investigative studies using nerve agents (G-agents). At this point it appeared that the deviance from the established policy could be attributed to a failure of staff officers at Department of the Army level to comply with the letter and the intent of policy established by the Secretary of Defense and expanded on by the Secretary of the Army.

In early November 1958 the Medical Laboratory at Edgewood submitted, through Chemical Corps channels, a request to use female volunteers in conjunction with the psychochemical research program. The request was then forwarded to The Surgeon General for comment, who recommended that the request be disapproved on the basis that the early stage of research in the area of psychochemical research and the serious legal and public relations implications involved in the use of female volunteers made it inadvisable to use females at this time.[35] Apparently, the Chief Chemical Officer agreed since that was the basis cited in his disapproval of the request. Subsequently, the Deputy Commander of the Chemical Warfare Laboratory, in an internal memorandum to the laboratory director stated that females could not be used on the basis that their use was strictly prohibited by the provisions of Chief of Staff Memorandum 385.[36] At this time we find one request, use of female volunteers, but two different reasons why they could not be used; one of which involved an interpretation of Chief of Staff Memorandum 385.

Thus, it appears that each request which involved application of the provisions of Chief of Staff Memorandum 385 resulted in an interpretation of the policy. More startling was the lack of consistency in the interpretations, ranging from the most strict to the widest possible latitude.

Another example of the highly flexible interpretations of policy occurred in November 1958, when the Chemical Warfare Laboratory Commander submitted a request to have an additional physician authorized to accept direct responsibility for the conduct of experimentations on human volunteers during the absence of the primary doctor. This doctor was to be in addition to the responsible physician required to be appointed by the Secretary of the Army in accordance with DOD policy. The Surgeon General recommended that another doctor be authorized to accept direct responsibility in the absence of the responsible physician and included an additional control to be used if the request was approved. However, the Chief, Research and Development, disapproved the req est and stated that: "as interpreted in all actions to date, the provisions of Chief of Staff Memorandum 385 do not permit the dilution of personal responsibility in the prosecution of the human volunteer program." Included with this disapproval was a copy of an opinion by The Judge Advocate General (TJAG) in which it was opined that there was no legal requirement that anyone be designated to assume direct responsibility when the designated doctor was absent.[37] To the contrary, the policy clearly contemplated one person should be so designated and would retain responsibility at all times. However, it also contemplated that other qualified persons would be placed in charge of specific experiments, subject to direction and control of the designated doctor. Again, we have an example of inconsistent interpretation.

Finally, in June 1969 a proposal titled, "Physiological Stress Aspects of Chemical Agents," was submitted by the Director of the Biomedical Laboratory at Edgewood Arsenal.[66] The proposal clearly indicated the intent to use safe amounts of chemical agents in human volunteers in connection with selected physiological stress experiments. However, it did not specify which chemical agents were to be used. The Office of The Surgeon General reviewed the protocol in the light that chemical agents would be used, although the protocol stated that a separate request for approval of actual chemical agents would be submitted.[67] The Office of the Chief of Research and Development approved the request and ruled that since chemical agents were not included in the protocol, Secretary of the Army approval was not required under AR 70-25.[68]

On 12 September 1969 the Office of The Surgeon General returned the approved request to Edgewood Arsenal.[69] Although it is known that experiments under this protocol were conducted at Edgewood, no evidence was found of the Secretary of the Army's approval of the specific chemical agents used. The submission of this particular protocol without mention of the chemical agents to be employed seemed to have negated the purpose of retaining authority at any level above the laboratory. The Army regulation in force at that time (AR 70-25) required the "detailed plan" to be submitted to The Surgeon General. The plan could hardly be considered a "detailed plan of experiment" without inclusion of the chemical agents intended to be used on the volunteers. It is conceivable that with approval of the protocol, less the chemical agents, the investigators could employ chemical agents previously approved in connection with the new plan.

Even though there were significant advances and changes in the research and the volunteer programs between 1953 and 1958, there was no indication of corresponding changes or updating of the policy directives.

By December 1958 there appeared to be concern about which chemical compounds were approved for use in volunteer subjects. Evidence of this concern was found in correspondence between the Director of the Medical Research Laboratories (Edgewood Arsenal) to the Commander, Chemical Warfare Laboratories (Edgewood Arsenal), and the Commanding General, Chemical Research and Development Command (Washington, DC), during the month of December 1958.[38] The gist of these documents was that the Medical Laboratories had initiated or intended to initiate research programs using volunteers to test chemical agent EA 1779 (CS), a riot control agent that causes extreme irritation to mucous membranes, and agent EA 1476 (tetrahydrocannabinols, a marihuana like compound). This was in addition to approvals already received for experiments with G-, V-, and K-agents. The documents indicated that the Chemical Research and Development Command agreed that research approval had been granted for G-agents (GA and GB), V-agent (VX), and K-agent (LSD-25); however, the Medical Laboratory was directed to suspend EA 1476 volunteer studies until Secretary of the Army approval was granted.[39] Available records indicated that the protocol for EA 1476 had not been submitted as of the end of December 1958, although there was an inference that some volunteer studies had been conducted. Additionally, the Medical Laboratory was permitted to continue volunteer studies with EA 1779 (CS), provided the protocol was submitted to their next higher command (Chemical Warfare Laboratory) by 30 December 1958.[40] The records indicated that the protocol for EA 1779 was submitted to the Commander, U.S. Army Chemical Research and Development Command, on 30 December 1958.[41] This series of documents indicated that the various Chemical Commands were in substantial agreement in regard to which protocols by class and agent were authorized for use in volunteer studies. The documents also indicated other areas of concern, to include: the desire to be in full compliance with Chief of Staff Memorandum 385 (CS:385) as evidenced by the suspension of the EA 1476 (marihuana) experiments; and the desire to avoid delays in the program while pending submission of the necessary protocol as evidenced by the granting of interim permission to continue EA 1779 (CS) studies while awaiting formal approval.

In February 1959 the Commander, Chemical Warfare Laboratories, reportedly learned that a woman had been exposed to EA 1779 (CS) in a planned experiment at the Medical Research Laboratory at Edgewood.[36] As a result of this incident, the Chemical Warfare Laboratories Commander sent his laboratory commanders a memorandum in which he stated that the use of females in human volunteer research programs was not authorized. Additionally, he emphasized that there were three definite control measures governing any particular experiment: the basic policy document on the use of human volunteers (Chief of Staff Memorandum 385); the specific protocol that was developed for use of a particular agent; and the detailed plan for the actual exposure of human volunteers which required approval by the individual designated by the Department of the Army as responsible for the use of chemical warfare agents on human volunteers.[36]

Following the 30 December 1958 submission of the protocol for EA 1779, no evidence was discovered which indicated actual Secretary of the Army approval for use of this agent. However, in July 1959 EA 1779 did appear on a list of agents approved to be used on humans which was published by the Chemical Warfare Laboratories. Also in July 1959, a directive from the Commander, Chemical Warfare Laboratories, Edgewood Arsenal, established that no individual could use on himself any agent for which an approved protocol was not available; another indication of tightening of controls.

In July 1959 the protocol for research involving chemical agent EA 1476 (marihuana) and related compounds and for phencyclidene (sernyl) benzilates and related compounds was submitted through Chemical Command channels. One of the accompanying documents included a declaration that prior to learning of the interpretation that each class of chemical agents necessitated separate approval from the Secretary of the Army for volunteer testing, chemical agent EA 1476 had been tested in about 36 volunteers.[44] There was no indication of who decided that each class of chemical agent had to be approved separately, or who decided on "class" approval as opposed to individual agent approval, which appeared to be the intent of the original directive from the Secretary of Defense ("Wilson Memorandum"). Although the initial request of 17 July 1959 was for two different classes of compounds (tetrahydrocannabinols and benzilates), the only protocol found for the period of time was the former. Moreover, the request from the Chief Chemical Officer to The Surgeon General for comments and/or concurrence addressed only EA 1476 and related compounds. On 21 July 1959 the protocol was concurred in by The Surgeon General. It is assumed that the protocol was then processed through normal command channels, although no documentation was found which indicated such staffing prior to the Secretary of the Army action in October 1959. On 8 October 1959 Secretary of the Army Wilber M. Brucker forwarded a memorandum to the Chief of Staff, U.S. Army, which stated: "approval is granted for the conduct of research investigations using volunteers for studies in defense against nonlethal incapacitating chemical warfare agents. These experiments will conform to the proposed plans submitted by the Chief Chemical Officer and reviewed by The Surgeon General, U.S. Army (Inclosure 1)." The memorandum further provided: "additional authority is granted to pursue similar volunteer studies with other nonlethal incapacitating chemical warfare agents provided The Surgeon General, U.S. Army, concurs with the protocol and procedures proposed by the Chief Chemical Officer, U.S. Army."[45] Clearly, Secretary Brucker delegated approval authority to two special staff members of the Department of the Army (Chief Chemical Officer and The Surgeon General) as regarded future "nonlethal incapacitating chemical warfare agents." It was not evident how often and to what degree that delegation was used. The nonavailability of documents in this regard may be attributed to the dilution of a formal approval procedure. Secretary Brucker's action did not require a signature approval "by either the Chemical Officer or The Surgeon General," nor was there any evidence that he required a copy of an approved plan to be provided either to his office, the Office of the Army Chief of Staff, Director of Research and Development, or the Secretary of Defense as required by the "Wilson Memorandum." It was possible that future approvals were informally coordinated with The Surgeon General and verbally approved by the Office of the Chief Chemical Officer. This possibility was supported, as mentioned earlier in this report, in that during the late 1950s and early 1960s interest and research in nonlethal incapacitating chemical warfare agents was very intense.

Secretary Brucker's approval was transmitted from the Chief, Research and Development, to the Chief Chemical Officer and The Surgeon General on 13 October 1959 without further guidance. On 16 October 1959 the Office of the Chief Chemical Officer relayed the approval to the Commanding General, Chemical Corps Research and Development (R&D) Command, again without adding amplification or clarification. The Chemical R&D Command forwarded it to the Chemical Warfare Laboratories on 23 October 1959 with a caution that experiments must conform to the proposal already approved for EA 2148 and EA 1476 (marihuana compounds) and related compounds and benzilates and related compounds. On 17 November 1959 the approval reached the Director, Medical Research Laboratory, Edgewood Arsenal, and directed that volunteer studies would be limited to EA 2148 and homologs, EA 1476 and homologs, LSD-25, CS, and benzilates.[46] It was of interest that the 17 November 1959 document did not include the term "related compounds"; this could have been an oversight or an effort to limit the latitude permitted the laboratory investigators. Taken literally, the omission of "related compounds" after benzilates would preclude experimentation, without additional approval, of candidate agents other than benzilates in the glycolate class. The original approval of benzilates and "related compounds" apparently would have permitted experiments with any glycolate agent. However, the evidence does not clearly indicate that this was an intentional restriction, or that it was perceived as a restriction by the research investigators.

It was also not surprising that there was a lack of evidence of new chemical agent protocols being submitted during this period. As far as the medical research investigators were concerned, approval was at hand to use volunteers in research involving the following: G-agents (nerve); V-agents (nerve); K-agents (psychochemicals); CS (irritants); tetrahydrocannabinols (marihuana); and benzilates (which could be interpreted to include other glycolates).

Benzilate Research

As was discussed earlier, the search for incapacitating agents intensified when the Kennedy administration took office. Specifically, Department of Defense "Project 112" placed a high priority on development of a chemical incapacitating agent. Records indicated that by 1962 the primary agent to meet this requirement was a benzilate called agent "BZ" or "EA 2277." Plans for this agent apparently called for development of munitions, stockpiles, and storage facilities, as well as essential research. By April 1962 the program had progressed to the point that on 23 April 1963 the Assistant Secretary of the Army (Research and Development) appointed a project officer to provide overall supervision of the project. On 20 June 1962 the Secretary of the Army signed a memorandum to the Secretary of Defense notifying him that the Army had already initiated action to have the doctrine for employment, storage, and handling of agent "BZ" completed prior to delivery of the munitions.[61] It apparently was assumed that formal Secretary of the Army approval for the agent research was included in Secretary Brucker's 8 October 1959 approval for use of volunteers in tests of "Phencyclidene ('Sernyl'), benzilates and related compounds."[45]

In March of 1972 the Director of the Biomedical Laboratory at Edgewood Arsenal submitted a proposed protocol for the "glycolate agents."[70] The request stated that Secretary of the Army approval had been obtained in earlier years, but that the Office of The Surgeon General and Office of the Chief, Research and Development, had suggested resubmission. No evidence was found which confirmed that either of the proposals were approved by the Secretary of the Army. However, it is possible that reference to earlier approval by the Secretary of the Army related to Secretary Brucker's approval of "benzilates and related compounds" in October 1959.[45]

Regulatory Controls

On 26 March 1962 the first Army regulation governing the "Use of Volunteers as Subjects of Research" was published (AR 70-25).[48] The purpose of the regulation was to "prescribe policies and procedures governing the use of volunteers as subjects in Department of the Army research, including research in nuclear, biological, and chemical warfare, wherein human beings are deliberately exposed to unusual or potentially hazardous conditions. These regulations are applicable worldwide, wherever volunteers are used as subjects in Department of the Army research." This regulation did not indicate supersedure of any previous directive(s), however, it appeared to be intended for that purpose. It provided for certain exceptions to policy for those performing normal hazardous duties, such as flight and jump training, fire and gas drills, and the like, similar to those discussed during the early Chemical Corps Advisory Council meetings. It listed basic principles to be observed by investigators, which were nearly identical to those recommended to the Secretary of Defense by the Armed Forces Medical Policy Board in early 1953. The regulation provided that: "a physician approved by The Surgeon General will be responsible for the medical care of volunteers. The physician may or may not be the project leader, but will have authority to terminate the experiment at any time that he believes death, injury, or bodily harm is likely to result." This provision appeared to be a change in the interpretation of guidance provided by the "Wilson Memorandum," which apparently intended that the service secretary would approve, in writing, the physician in charge, as well as the protocol for the experiment.

Appointment of Responsible Physician

A brief discussion of the history of the appointment of "responsible physicians" for the medical volunteer program is in order at this point.

Evidence indicated that in April 1956 the Secretary of the Army approved the appointment of Dr. Van M. Sim as physician responsible for volunteers in chemical warfare research.[49] The records further indicated that in November 1958 an effort was made to expand the "one physician in charge" requirement (as mentioned earlier in this chapter), when the Chief Chemical Officer requested the Secretary of the Army to appoint Dr. Kimura, assigned to the Medical Research Laboratory, as the alternate physician in charge, to act as such when Dr. Van M. Sim was temporarily absent from the laboratory. However, the request was not approved[50] and the requirement for a responsible physician remained unchanged.

Authority to appoint the physician in charge had remained with the Secretary of the Army. This was indicated on 18 June 1959 when the Under Secretary of the Army, acting for the Secretary, appointed Colonel Lindsey, newly assigned Director of the Medical Laboratory, to replace Dr. Van M. Sim as the responsible physician.[51] This level of authority apparently continued until 17 July 1962 (after publication of AR 70-25) when a request to have Colonel Lindsey's replacement as director (Colonel Bauer) appointed as responsible physician was forwarded to the Office of the Chief Chemical Officer, who forwarded the request through The Surgeon General to the Chief, Research and Development. On 6 August 1962 The Surgeon General recommended approval and on 17 August 1962 the Chief, Research and Development, approved the designation of Colonel Bauer.[52] Although the regulation (AR 70-25) provided for The Surgeon General to approve the responsible physician, in this instance the appointment was made by the Chief, Research and Development. On 20 March 1963 the Commander, Chemical Research and Development Laboratory, submitted a request to have Dr. Van M. Sim appointed responsible physician to replace Colonel Bauer. The request was forwarded through the U.S. Army Munitions Command and U.S. Army Materiel Command to The Surgeon General, who, on 16 April 1963, recommended to the Chief, Research and Development, that Dr. Sim be appointed on an interim basis until a Medical Corps officer was assigned as Director of the Laboratory. On 18 April 1963 the Chief, Research and Development, approved The Surgeon General's recommendation and further requested that the Commander, U.S. Army Materiel Command, upon the assignment of a Medical Corps officer as Director of Medical Research, take necessary action to designate him as the responsible physician.[53] Several months later, on 26 September 1963, Colonel Blair was appointed to replace Dr. Sim, a position he held for eleven years.[54] Although it could not be determined at what level of authority this appointment was made, correspondence directed to the Commander, U.S. Munitions Command, was obtained and it is assumed that the Commander, U.S. Army Materiel Command, approved the designation. By 1974 the practice of service secretary approval of the "Medical Officer Responsible for Volunteers" had come full cycle. On 9 September 1974 Colonel McClure, Director, Biomedical Laboratory, was appointed by the Secretary of the Army, even though the governing regulation (AR 70-25, dated 31 July 1974) required, as did the earlier version, that The Surgeon General approve the appointment of the physician responsible for the medical care of volunteers.[73]

Although the level of approval authority for appointment of the physician responsible for volunteers in research apparently was changed, the authority to approve a specific protocol was retained by the Secretary. Paragraph 6, AR 70-25, dated 26 March 1962, Approval to Conduct Experiments, provided that: "It is the responsibility of the head of each major command and other agency to submit to The Surgeon General a written proposal for studies which come within the purview of this directive. The proposal will include for each study the name of the person to be in charge, name of the proposed attending physician, and the detailed plan of the experiment. The Surgeon General will review the proposal and forward it with his comments and recommendations on medical aspects to the Chief of Research and Development for approval. When a proposal pertains to research with nuclear, biological or chemical agents, the Chief of Research and Development will submit the proposal, together with The Surgeon General's review, to the Secretary of the Army for approval. No research with nuclear, biological or chemical agents using volunteers will be undertaken without the consent of the Secretary of the Army."[48] AR 70-25 was revised in July 1974. The revision transferred the final approval authority from the Chief of Research and Development to The Surgeon General for all research using volunteers, except research involving nuclear and chemical warfare agents. Approval for nuclear and chemical warfare agents was retained by the Secretary of the Army.

Medical Corps/Chemical Corps Agreements

The procedures for gaining approval of the use of human volunteers in chemical warfare agent experiments apparently was well defined, to include mandatory review and comment by The Surgeon General. In effect, once The Surgeon General had reviewed a protocol, his role in that phase of chemical agent research was finished, unless specific requests for assistance or advice were received. Thus, the medical expertise available from the Office of The Surgeon General apparently was absent during the actual conduct of experiments. A means to alleviate this problem may have been available through the initiation of a series of Joint Medical-Chemical Agreements.

The first known agreement was dated August 1958 and was titled: "The Joint Medical-Chemical Agreement to Conduct Research and Development." This agreement, which was signed by The Surgeon General and the Chief Chemical Officer, provided that The Surgeon General would assign a medical doctor as Director of the Medical Research Laboratory (Biomedical Laboratory) who would have his performance rated by the Commanding Officer of the Chemical Warfare Laboratories at Edgewood Arsenal. The Director's performance would be indorsed by the Commanding General, Army Medical Research and Development Command. Thus, the Director would work primarily for the Chemical Corps and have the initial part of his performance report completed by his Chemical Corps superior; and secondarily he would serve as the chemical warfare advisor to the Commanding General, Army Medical Research and Development Command (which was directly under The Surgeon General), who would be the indorsing officer for the duty performance report.[56] The agreement appeared to be an adequate method for insuring that The Surgeon General's office was kept informed of the Medical Research Laboratory's efforts. The agreement was renewed in March 1959 with the appointment of a new Chief Chemical Officer[57] and again in January 1963, when the Chemical Corps' responsibilities were transferred to the Army Materiel Command.[58] Another reference to this agreement was found in an August 1972 version, which was amended in November 1972, to allow for: annual program planning and evaluation to be made jointly between The Surgeon General and the Commanding General, U.S. Army Materiel Command; performance evaluation of the Biomedical Laboratory director to be made by Edgewood Arsenal Technical Director and indorsed by the Commander, Medical Research and Development Command; and for the submission of research protocols to U.S. Army Materiel Command for new classes of chemical agents not previously approved. These protocols were to be reviewed by The Surgeon General and forwarded to the Secretary of the Army for approval.[59]

Other Regulatory Controls

In 1964 two separate Department of Defense Instructions were published which seemed to separate chemical and biological research from investigational drugs research. The first, Department of Defense Instruction

Number 5160.5, dated 7 February 1964, subject: Responsibilities for Research, Development, Test and Evaluation on Chemical and Biological Weapons and Defense,[62] directed that each service would be responsible for preparation and conduct of its own programs and that the Army would be responsible for joint requirements. The second publication was Department of Defense Instruction Number 5030.29, dated 12 May 1964, subject: Investigational Use of Drugs by DOD. It stated that: "DOD assumes full responsibility for the protection of humans involved in research under its sponsorship, whether this involves investigational drugs or other hazards." To monitor this responsibility, DOD directed that each military department establish, within the office of its respective surgeon general, a formal board of professional personnel to consider each research proposal from within that military department or from its contractors, or grantees, which may involve the use of human subjects in clinical investigation of new drugs. (To implement this, the Army established the Army Investigational Drug Review Board.) Furthermore, the DOD instruction provided that before a clinical test with an investigational drug was performed under the sponsorship of a military department, the plan of the test and other pertinent details would be submitted to the appropriate review board. The board, in turn, would indicate its approval and forward the plan with its approval to the service surgeon general for confirmation. DOD further directed that each service would prepare a plan to implement the requirements discussed above within 60 days. Attached to the DOD instruction was a memorandum of understanding between the Department of Health, Education and Welfare and DOD concerning: "Investigational Use of Drugs by the DOD."[63]

Although both of the DOD instructions were signed by the Director of Defense Research and Engineering, they did not make reference to each other or mention a possible relationship. Nevertheless, the Army apparently perceived the requirements as separate and distinct. As an example, it appeared that between 1964 and 1974 a basic drug such as LSD could be processed through two different channels, depending on its proposed use. If the investigator was within the Medical Research and Development family, the protocol would go before the Army Investigational Drug Review Board (AIDRB) and receive final approval from The Surgeon General, if warranted (AR 40-7). On the other hand, the protocol from investigators employed at the Biomedical Laboratory at Edgewood Arsenal would be routed through the Army Materiel Command channels to The Surgeon General for concurrence on the medical aspects of the protocol (AR 70-25) and final approval was to come from the Secretary of the Army after receiving The Surgeon General's comments. AR 70-25 did not, and still does not, require the drug (LSD in this case) to be reviewed by the Drug Review Board as part of The Surgeon General's procedure. To compound the problem, those drugs which were already being investigated on human subjects as investigational drugs were not required by regulation to be submitteddfor review after the AIDRB was established. Thus, two different systems existed to seek approval for the same drug. Neither system, chemical or medical, apparently provided for retroactive application to ongoing agent or drug research previously approved.

Finally, in November 1964 the Department of the Army published AR 40-7 (13 November 1964), subject: Clinical Use of Investigational Drugs.[64] This regulation superseded AR 40-2, dated 14 November 1960, and directed that new drugs required for investigational use would not be used without prior approval of The Surgeon General. AR 40-7 also provided for extensive review of the proposed protocol by the AIDRB. This regulation subsequently was revised and republished on 21 July 1967, 30 September 1969, and 4 April 1975, without major modification or change.[65]

On 10 September 1975 LTG Richard R. Taylor, The Surgeon General of the Army, testified before Congress that: "in October 1974, The Surgeon General established the Human Use Review Office under the direction of the Assistant Surgeon General for Research and Development. The Human Use Review Office was charged with administering and coordinating activities of the Army Investigational Drug Review Board, the U.S. Army Medical Research and Development Command Contract Review Board and The Surgeon General's Human Use Committee and Clinical Investigation Committee, to insure uniform application of ethical standards for human research studies conducted within or sponsored by the Army Medical Department and other Army Agencies. The Human Use Review Committee is the central Army processing point for all extramural and intramural human subject research which require approval under provisions of Army Regulations." While discussing Defense Against Chemical Weapons, Lieutenant General Taylor reported: "Furthermore, the review mechanisms applied to Edgewood have been tightened over the last two years so that protocols are reviewed by the Army Investigational Drug Review Board and Human Subjects Research Review Board and relevant Department of Defense and Food and Drug Administration regulations are followed."[72]

Suspension of Human Volunteer Program

On 28 July 1975 Acting Secretary of the Army Norman R. Augustine suspended testing of chemical compounds on human volunteers at Edgewood Arsenal.